

# Exhibit 3

Art Unit 184

MAILED

Paper No. 15

Appeal No. 89-0918

SEP 28 1989

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ON BRIEF

PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

## UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Ex parte Robert M. Goodman  
Vic C. Knauf  
Catherine M. Houck  
and  
Luca Comai

Application for Patent filed July 29, 1985, Serial No.  
760,236. Mammalian Peptide Expression in Plant Cells.

Bertram I. Rowland et al. for appellants.

Supervisory Primary Examiner - Charles F. Warren.  
Examiner - D. Fox.

Before Goldstein, W. Smith and Haight, Examiners-in-Chief.  
Goldstein, Examiner-in-Chief.

This appeal is from the examiner's final rejection of claims 1 to 13. There are no allowed claims. Illustrative claims 1, 7 and 8 are reproduced below.

1. A method for producing a mammalian peptide which comprises:

growing plant cells containing an integrated sequence comprising,

a first expression cassette having in the direction of transcription (1) a transcriptional and translational initiation region functional in said plant cells, (2) a structural gene coding for said mammalian peptide, and (3) a termination region,

whereby said structural gene is expressed to produce said mammalian peptide, and

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isolating said mammalian peptide substantially free of plant cell components.

7. A method for producing an interferon which comprises,

growing plant cells containing an integrated sequence comprising,

a first expression cassette having in the direction of transcription (1) a transcriptional and translational initiation region functional in said plant cells and derived from a region which regulates expression of a T-DNA gene, (2) a structural gene coding for an interferon, and (3) a termination region functional in said plant cells,

whereby said structural gene is expressed to produce said interferon, and

isolating said interferon substantially free of plant cell components.

8. A method according to Claim 7, wherein said plant cells are dicotyledon plant cells and said integrated sequence comprises a second expression cassette having in the direction of transcription (1) a transcriptional and translational initiation region functional in said plant cells, (2) a structural gene coding for an enzyme which imparts antibiotic resistance, and (3) a T-DNA boundary.

References relied upon by the examiner on appeal are:

Gray et al. (Gray), Nature, Vol. 295, February 1982, pages 503-508.

Murai et al. (Murai), Science, Vol. 222, November 1983, pages 476-482.

Herrera-Estrella et al. (Herrera-Estrella), Nature, Vol. 310, July 1984, pages 115-120.

Velten et al. (Velten), The EMBO Journal, Vol. 3, No. 12, 1984, pages 2723-2730.

Goodman et al. (Goodman), Science, Vol. 236, April 1987, pages 48-54.

Reference of record discussed in the following opinion:

Shaw et al. (Shaw), "A General Method for the Transfer of Cloned Genes to Plant Cells," Gene, Vol. 23, No. 3, 1983, pages 315-330.

All of the appealed claims have been finally rejected under either or both of 35 USC 103 and 112. There have been some clear errors in keeping track of which claims were subject to

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exactly which grounds of rejection throughout the prosecution of this application. However, it is clear that these inadvertent errors have not clouded the issues, which have been clearly defined by both the examiner and appellants on the record. The claims which, in our view, correspond to the different grounds of rejection based on the correspondence of the claimed subject matter to the issues raised by the rejection in each case are as follows.

With respect to the rejection under 35 USC 103 for obviousness, claims 1 to 4, 6 to 8 and 10 to 12 have been rejected as being unpatentable over the combined teachings of Murai and Gray. Herrera-Estrella has been considered additionally with respect to claim 5, and Velten has been considered additionally with respect to claims 9 and 13. The situation with regard to the rejection over prior art is simplified by appellants' acknowledgment that patentability of all of the claims rests on the unobviousness of the broadest claims over the basic combination of Murai and Gray.

The basis of the rejection under 35 USC 112 for lack of an enabling disclosure is the failure to specify the mammalian gene to be expressed, the vector for its expression and (in the process claims) the host in which the vector operates. In the final rejection, all three of these criteria were considered together. In the answer on appeal, the examiner has stated two separate rejections, one limited to the specific gene and the other limited to the vector and host. Since we agree with the examiner's position with regard to all three limitations, we shall simply distinguish those claims which recite all three (or, in the case of the "construct" or "expression cassette" claims, the two relevant ones) from those which do not, i.e., we shall treat the two rejections as one, in the manner of the final rejection. Thus, the claims which are subject to the rejection under 35 USC 112,

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because they do not recite all of the essential limitations, are claims 1 to 7 and 10 to 12. The claims which are free of this rejection are claims 8, 9 and 13. To illustrate this distinction, we have above reproduced claim 8 together with claim 7, from which it depends, and claim 1.

With respect to the rejection under 35 USC 103, we find appellants' arguments convincing of error on the part of the examiner. The state of the art illustrated on this entire record, including the discussion of the prior art in the original specification as filed, the references now relied on by the examiner and all of the additional references of record, is clearly such that motivation existed to do that which appellants have done and here claimed. The evidence also illustrates that success has been achieved in performing related but not identical biotechnological syntheses. A nonmammalian eukaryotic gene has been expressed in a plant cell (Murai). A mammalian gene has been expressed in a eukaryotic animal cell, but not a plant cell (Gray). However, the only report before us concerning the expression of a mammalian gene in cells of higher plants is the Shaw article, which reports the transfer of the mammalian gene to the plant genome but failure to obtain expression, which apparently failed at the transcription stage (see the last sentence of the summary).

The examiner has failed to indicate how, from the prior art evidence of record, one of ordinary skill in the relevant art would have known what modifications to make in the various prior art procedures to obtain a result different from that reported in the Shaw article for example. In the absence of such an explanation, we find that appellants' claims would not have been obvious under 35 USC 103 based on this record and the examiner's explication thereof.

We shall affirm the examiner's rejection of claims 1 to 7, and 10 to 12 under the first paragraph of 35 USC 112.

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It appears to have been accepted by the examiner that the experimental portion of appellants' specification enables one of ordinary skill in the relevant art to repeat that which appellants have done, i.e., obtain the expression of an interferon gene through the use of a transformed Ti-plasmid in dicotyledonous plant cells. In view of the very same high order of unpredictability of success in extrapolating reported procedures to different systems, e.g., different genes, different vectors and different hosts, discussed above, appellants' arguments that their disclosure enables one of ordinary skill to practice the inventions claimed more generally in the broader claims without the exercise of undue experimentation are unreasonable on their face.

From the arguments presented by appellants in their brief on appeal, it appears that they have also taken the more extreme position that no amount of experimentation would be undue and that, having carried out one successful, specific biosynthesis, they are per se entitled to claim the entire concept disclosed as a research goal in the prior art of record.

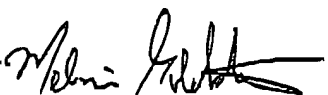
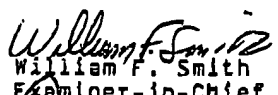
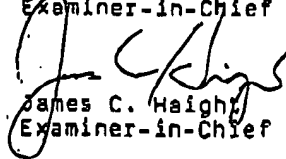
The factors to be taken into consideration in determining whether or not the amount of experimentation required to practice the subject matter of a patent claim is unduly burdensome under 35 USC 112 have been discussed at great length in reported prior decisions. See, for example, Ex parte Forman, 230 USPQ 546 (BPAI 1986); Ex parte Jackson, 217 USPQ 804 (Bd. App. 1982). We shall not burden the present record with a repetition of that entire discussion here. It is amply clear from appellants' arguments that they have not taken cognizance of those factors. They have expressed their opinion that it is not necessary to enable one of ordinary skill in the relevant art "to avoid the expenditure of sweat and monies which applicants expended at a time

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when they could not be certain of success" (brief on appeal, page 8) and that it is acceptable to require those of ordinary skill, in practicing the invention, "to carry out the peeling of onions, the cutting of meat and the preparing of stew in order to have the dinner" (brief on appeal, page 8). These statements are entirely antithetical to the policy expressed in the enablement requirement of 35 USC 112. In the present case, appellants have emphasized the "high degree of unpredictability of success" in modifying specific known procedures in this field (brief on appeal, page 21), and nowhere on this record can one find any indication of what specific modifications of the Shaw process, for example, were responsible for appellants' success relative to the incompletely satisfactory results obtained by Shaw. Thus, their position on the issue of undue experimentation is particularly untenable on this record.

The examiner's rejection of claims 1 to 7 and 10 to 12 is affirmed. The rejection of claims 8, 9 and 13 is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR 1.136(a). See the final rule notice, 54 F.R. 29548 (July 13, 1989), 1105 O.G. 5 (August 1, 1989).

AFFIRMED-IN-PART  
Melvin Goldstein  
Examiner-in-Chief  
William F. Smith  
Examiner-in-Chief  
James C. Haight  
Examiner-in-Chief

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